IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	S. Bailey, et al.	Attorney Docket:	6006-009
Serial No.:	09/783,633	Examiner:	C. Miller
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Title: In Vivo Sensor and Method of Making Same

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AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

Dear Sir:

This is in response to the non-final Office Action mailed dated September 17, 2009. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Summary of Examiner's Interview begins on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will supercede all prior versions, and listings of claims in the instant application.

Claims 1-67 (Canceled).

68. (Currently Amended) A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, ~~at least one region of~~ the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, wherein the second transition temperature and the second transition coefficient ~~allowing~~ allows for a change in the geometry or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the change in geometry or conformation changes the positioning of the second region ~~structural elements~~ relative to the geometry of the ~~second material~~ first region during the second transition temperature; and a detection mechanism configured to detect the change in the geometry or conformation of the in vivo sensor device, and wherein the second material comprises at least one of a shape memory material and a superelastic material.

69. (Previously Amended) The system of claim 68, wherein the first material comprises at least one of a shape memory material, a superelastic material, a plastically deformable material, an elastically deformable material, a stainless steel and a nickel-titanium alloy.

70. (Cancelled)

71. (Previously Amended) The system of claim 68, wherein the second material has a martensite transition temperature that is higher than a martensite transition temperature of the first material.

72. (Currently Amended) The system of claim 68, wherein ~~the~~ the second material ~~is configured to measure~~ responds to at least one physiological condition.

73. (Previously Presented) The system of claim 72, wherein the physiological condition is fluid flow rate.

74. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is temperature.

75. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is plaque.

76. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is an electrochemical change.

77. (Currently Amended) A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, ~~at least one region of~~ the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, the second ~~material~~ region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the first position is coplanar with the surface of the first region ~~structural elements~~ and the second position projects outwardly from the surface of the ~~structural~~

~~elements~~ first region during the second transition temperature; and a detection mechanism configured to detect the second position of the in vivo sensor device, wherein the second material comprises at least one of a shape memory material and a superelastic material.

78. (Previously Presented) The system of claim 77, wherein the first material comprises at least one of a shape memory material, a superelastic material, a plastically deformable material, an elastically deformable material, a stainless steel and a nickel-titanium alloy.

79. (Cancelled)

80. (Previously Presented) The system of claim 77, wherein the second material has a martensite transition temperature that is higher than a martensite transition temperature of the first material.

81. (Previously Presented) The system of claim 77, wherein the second material is configured to respond to at least one physiological condition.

82. (Previously Presented) The system of claim 81, wherein the physiological condition is fluid flow rate.

83. (Previously Presented) The system of claim 81, wherein the physiological condition is temperature.

84. (Previously Presented) The system of claim 81, wherein the physiological condition is plaque.

85. (Previously Presented) The system of claim 81, wherein the physiological condition is an electrochemical change.

REMARKS

Applicant has amended Claims 68, 72, and 77 and cancelled claims 1-67, 70, and 79. Support for the claim amendments have support throughout the specification, including, but not limited to the following: Claim 68 on page 22, lines 1-23 and previous claim 70; and Claim 77 on page 6, lines 19-30 and page 8, lines 15-20 and previous Claim 79. No new matter has been entered by the claim amendments, and the Applicant respectfully requests the Examiner to enter the claim amendments accordingly.

SUMMARY OF EXAMINER'S INTERVIEW

Applicant graciously thanks the Examiner for conducting the Examiner's Interview on December 9, 2009 with the Applicant. The Applicant and the Examiner discussed at length the §112, first paragraph issues with Claims 68 and 77, and Examiner Miller indicated that she wanted to see that the structural elements include a first region of a first material, a second region of a second material, and the second region changes in geometry or conformation relative to the geometry of the first region. The Applicant and the Examiner discussed at length the Santini and Burmeister prior art references. The Applicant indicated that Burmeister include two separate structural elements that do not change position or geometry relative to themselves or to each other. Examiner Miller indicated possible allowable subject matter over Burmeister due to the second region changing during a second transition temperature and relative to a first region of the structural elements and indicated that she would take such amendments under consideration and examination of the prior art references.

ARGUMENTS

Claim Rejections under 35 U.S.C. §112

Claims 68-76

In the Office Action, the Patent Office rejected Claims 68-76 under §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated the following:

Claim 68 is indefinite. Line 13 requires the geometry change to change the position of the structural elements relative the geometry of the second material. This is rendered indefinite for two reasons. It is unclear how the geometry of the second material can change. That is, how can a "material" change geometry. It seems applicant intended to claim the geometry of the at least

one region instead of the second material is changed. Also, it is unclear how the position of the structural elements change with respect to the second material, when the second material are part of the structural elements themselves. It also seems that the position of the second material (at least one region) changes, not the position of the structural elements. It seems applicant intended to claim the position of the at least one region to change relative the remainder of the structural elements, however is it unclear as currently claimed. Claims 69-76 depend upon claim 68 and inherit all problems associated with the claim.

Claim 72 recites, "the second material is configured to measure at least one physiological condition". It is unclear how a material "measures". It seems applicant intended to claim "respond to" as in comparable claim 8 1, instead of "measure".

Claim 77 is indefinite. Line 8 requires the second material to change positions. It is unclear how a material changes position. It seems applicant may have intended to claim the at least one region to change positions instead of the second material. It is also unclear how the first position is coplanar with the surface of the structural elements, when the second material are part of the structural elements? How can a part be positioned relative to itself? Claims 78-85 depend upon claim 77 and inherit all problems associated with the claim.

The Applicant respectfully disagrees and traverses the rejection herewith. The Applicant has amended Claim 68 to state that the "wherein the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature". The Applicant has amended Claim 72 to state that the second material "responds to" at least one physiological condition. And, the Applicant has amended Claim 77 to state that the "wherein the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature". The first position is coplanar with the surface of the first region before changing position and changes position relative to the first region to "project outwardly" from the first region during the second transition temperature. As such, Claims 68, 72, and 77 are definite to particularly point out and distinctly claim the subject matter. The Applicant respectfully requests the Examiner to withdraw the §112, first paragraph, rejection accordingly.

Claim Rejections under 35 U.S.C. §103

Claims 68-69, 72, 74, 76, 77, 78, 81, and 83

The Examiner rejected Claims 68-69, 72, 74, 76, 77, 78, 81, and 83 under 35 U.S.C. §103(a) as being unpatentable over Santini, Jr. et al. (US 200410260391 Al, cited previously) in view of Palmaz (US 4,733,665). The Examiner stated the following:

Santini discloses an in vivo sensor device system (stent; seen in fig.9a-9c) substantially as claimed comprising a plurality of structural elements (individual smts of stent seen for example in fig.9a, other stent shapes disclosed P0095-P0098; P0064-P0067) defining the device, the

structural elements (struts) composed of a first material (substrate) having a first transitional temperature and coefficient (inherent property of the substrate/stent material) and at least one region (caps) of the structural elements composed of a second material (cap material) having a transitional temperature and coefficient higher than the first material (different microchip caps made of different materials with different transitional temperatures or deform at different rates, P0030, P0048, P0046), allowing a change in geometry or conformation in the second diametric state (final configuration) upon application of a force (heat or pressure), wherein the change in geometry changes the position of the structural elements (struts) relative the second material (caps; caps move to different position angled away from strut surface, see figures 4a-4c for example; P0045) and a detection mechanism (console, monitoring system, P0090, P0091). Santini discloses the in vivo sensor substantially as claimed, however is silent to whether the stent is diametrically expandable or not between a first and second diametric state. Stents are well known in the art to radially expand in order to function properly to open and maintain open a vessel. Santini does not recite any expansion, however it would seem inherent that since vascular stents are disclosed, they must be expandable. If not inherent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the stents of Santini to be expandable so as to be able to deliver them to the vasculature at a small diameter, minimizing trauma then enlarging to fully support the vessel wall. See as evidence Palmaz which shows several different known stent shapes that all expand to a larger diametric state to fully support the vessel.

The Applicant respectfully disagrees and traverses the rejection herewith. The Applicant has amended Claim 68 to include "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature"; and "wherein the second material comprises at least one of a shape memory material and a superelastic material". Santini does not teach or disclose that "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature"; and "wherein the second material comprises at least one of a shape memory material and a superelastic material". Since Santini fails to disclose each and every element specifically defined in amended Claim 68, the rejection of Claim 68 under §103(a) has been overcome and should be withdrawn. Moreover, Claims 69-76 depend from amended Claim 68. These claims are further believed allowable over Santini for the same reasons set forth with respect to their parent Claim 68 since each sets forth additional elements of Applicant's device.

Regarding Claim 77, Santini does not teach or suggest "at least one region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the first position is coplanar with the surface of the structural elements and the second position projects outwardly from the surface of the structural elements during the second transition temperature", and

"wherein the second material comprises at least one of a shape memory material and a superelastic material". Since Santini fails to disclose each and every element specifically defined in amended Claim 77, the rejection of Claim 77 under §103(a) has been overcome and should be withdrawn. Moreover, Claims 78-85 depend from amended Claim 77. These claims are further believed allowable over Santini for the same reasons set forth with respect to their parent Claim 77 since each sets forth additional elements of Applicant's device.

Claims 68-72, and 74

The Examiner rejected Claims 68-72, and 74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Burmeister (EP 0 759 730 B 1, cited previously) in view of Wolinsky et al. (US 6,840,956 B1, cited previously). The Examiner stated the following:

Regarding claim 68, Burmeister discloses an in vivo sensor device system (stent 10; seen in fig. 1, 5, or 6) comprising a plurality of structural elements (individual struts, 12+14) defining the device, the structural elements (struts) composed of a first material (struts 12, 62,52 made of an austenite material) having a first transitional temperature and coefficient to expand from a first diametric state (delivery state) to a second diametric state (self-expanded state; col.2, lines 16-19) and at least one region (struts 14, 54, and 64) of the structural elements composed of a second material (martensite superelastic material 34) having a transitional temperature and coefficient higher than the first material (see fig 4a, 4b showing transitional temperature greater for material 34; P0029, P0032), allowing a change in the geometry or conformation upon application of a force (balloon force; col.2, lines 20-23 causes geometry change after the self expansion), wherein the change in geometry changes the position of the structural elements (12, 62, 52) relative the geometry of the second material (14,64,54- these struts move radially outward towards the plane of the rest of the structural elements when forced outward by the balloon). Burmeister discloses the system substantially as claimed, however is silent to mention any detection mechanisms for measuring the geometry/conformation change of the second material (plastic final expansion) relative the structural elements (that have already been diametrically self expanded). Wolinsky teaches in the same field of stents (1 6; fig.2), the use of a detection mechanism (fluoroscopy; col.6, lines 12-15) in order to view the insertion, position and expansion of the stent to insure the stent was implanted correctly. Such imaging techniques are well known in the stent art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Burmeister's stent system with Wolinsky's teaching of using fluoroscopy (detection mechanism) with the implantation of stents, in order to provide a system that provides the surgeon with assistance and reassurance that the stent was positioned accurately in the vessel (as fluoroscopy views the stent during expansion, it also displays the structural elements/struts changing configuration).

Burmeister discloses the first material to comprise a shape memory material and the second material to comprise a superelastic material, wherein the second material has a higher martensite transition temperature (see fig.4b compared to fig.4a). Burmeister's second material (martensite struts) is configured to monitor a condition such as pressure (pressure is created by fluid flow or plaque build-up) or temperature (stent changes shape when expanded in response to pressure or temperature, P0030, P0032, P0012, thus is considered to measure these parameters).

The Applicant respectfully disagrees and traverses the rejection herewith. Burmeister and Wolinsky et al. do not teach or suggest "the change in geometry or conformation changes the positioning of the at least one region relative to the geometry of the structural elements during the second transition temperature", and "wherein the second material comprises at least one of a shape memory material and a superelastic material", as to render Claim 68 unpatentable. Any strut material 12, 62, 52 would not change positions relative to the martensite superelastic material 34, 54, 64, in any of the Burmeister embodiments or figures. Figure 3 is shown below, with material 32 and 34, where the martensite material 34 does not change in geometry relative to the austenite material 32 because the materials 32 and 34 are layered upon one another, such that the martensitic layer 34 holds back layer 32 to prevent layer 32 from fall expansion, as shown in Figure 3. Figure 5a and 5b show a similar construction in Burmeister, where rings 52 and 54 are austenitic and martensitic, respectively, and interconnected by struts 56, which rigidly hold the rings 52 and 54 together with a stainless steel material 56. Any expansion of ring 52 necessarily pulls and expands ring 54 through strut 56, or vice versa, probably best shown in the cross sectional view of Fig. 5b. Finally, Burmeister shows in Figure 6 a braided or interwoven construction with strands 62 in an austenitic and strands 64 are in the martensitic state, but again, with a braided or interwoven construction does not allow for movement of the strands 62 and 64 relative to each other. There no indication in Burmeister that strut material 12, 62, 52 could operate or move independent of strut material 34, 54, 64, i.e. both layers of material 52 & 54, 62 & 64, or 32 & 34) operate in coincidence with each other, rather than moving separate or relative to each other. As such, Burmeister and Wolinsky et al. fail to disclose each and every element specifically defined in amended Claim 68, the rejection of Claim 68 under §103(a) has been overcome and should be withdrawn. Moreover, Claims 69-76 depend from amended Claim 68. These claims are further believed allowable over Burmeister and Wolinsky et al. for the same reasons set forth with respect to their parent Claim 68 since each sets forth additional elements of Applicant's device.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and pass this application to issue. The Applicant respectfully requests a telephone conference to expedite the prosecution of the

application, the Examiner is invited to telephone the undersigned at the number provided below at the earliest convenience.

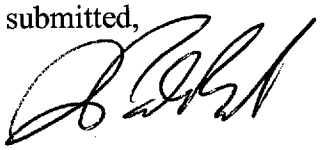
Any remarks in support of patentability of one claim should not be imputed to any claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertion regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

No fee is believed due with this Response. However, in the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge

the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted,



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